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10/775,554

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Meng Yang

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

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1633

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ATTACHMENT TO ADVISORY ACTION

11. CONT. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the rejection of claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over WO 02/28188 A1 (4/1/02), hereafter referred to as Kern, in view of Okabe et al. (1997) FEBS Lett., Vol. 467, 313-319. Please note that arguments regarding the teachings of Yang et al., newly submitted as evidence with the after-final response, are not persuasive as Yang et al. has not been entered or considered since applicant has failed to provide any reason why this evidence was not provided earlier in prosecution prior the mailing of the final office action on 1/22/09. The applicant argues that Kern et al. does not teach constitutive expression of GFP. This is not agreed. Page 13, paragraph 1, clearly teaches the constitutive expression of GFP. While the purpose of constitutive expression of GFP in a transgenic mouse discussed in this paragraph may be different from applicant's intended use, this is irrelevant as the patentability of the claimed product depends on its structure and not any particular intended use. Further, whether or not an inducible promoter would suit the intended use better than a constitutive promoter is likewise irrelevant as Kern et al. specifically teaches the embodiment of a transgenic animal where GFP is constitutively expressed. The applicant then argues that the successful production of an immunodeficient mouse that expresses GFP in all tissues is a surprising and unexpected result since the expression of GFP could be toxic in the background of immunodeficiency. In response, it is first noted that the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP § 716.01(c). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. MPEP 716.01(c). There is no evidence of record that expression of GFP would be any more toxic in an immunocompromised mouse than it would be in a immunocompetent mouse or that the skilled artisan at the time of filing would not have expected

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success in producing a transgenic GFP nu/nu mouse as taught by Kern et al. It has been noted in previous office actions that Kern et al. specifically teaches methods of making a mouse as claimed by stably integrating the detectable gene into the chromosome of a mouse embryonic stem cell and using the embryonic cell to develop strains of homozygous mice having two copies of the integrated construct in every cell, and then breeding the mice with nu/nu mice to produce mice that are homozygous for the transgene and homozygous for immunodeficiency. As noted previously, the guidance provided by Kern is in fact more detailed than that provided by the instant specification for making transgenic mice. As such, applicant's arguments are not found persuasive in overcoming the rejection of record.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, the new technology center fax number is (571) 273-8300. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/

Primary Examiner, A.U. 1633

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